

Serial No. 10/007,177
5962-01-CA

REMARKS

I. Status of the Application

This paper responds to a Non-Final Office Action mailed November 18, 2004. The application was originally filed with 24 claims. In an amendment filed on October 25, 2002, Applicant canceled claims 8 and 13-16, and amended claims 1, 5, 9, 10, 17, 19 and 23. In response to a Final Office Action, Applicant canceled claims 1-7, 9-12, 22 and 24, and amended claims 17-21 and 23. A subsequent non-Final Office Action withdrew finality. In response to the non-Final Office Action, Applicant amended claims 17, 20, and 21. Following a Final Office Action and Advisory Action, which were mailed on February 18, 2004 and June 4, 2004, Applicant filed a Request for Continued Examination (RCE). The RCE amended claim 17 and added claim 25. The present paper amends claim 17, and therefore claims 17-21, 23, and 25 are under consideration in the present application.

Applicant respectfully requests reconsideration of the pending claims in view of the above amendment and the following remarks. By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

II. Supplemental Information Disclosure Statement

Applicant filed a supplemental information disclosure statement on November 15, 2002. Applicant has not received a copy of PTO/SB/08, which lists references cited in the supplemental information disclosure statement. Applicant respectfully requests that the next Office Action include a copy of the PTO/SB/08 form, which has been initialed by the Examiner. The references cited in the supplemental IDS included documents cited in a search report from the European Patent Office (EPO) for a corresponding patent application filed in the EPO.

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III. Amendment of Claim 17

Applicant has amended claim 17 to clarify that the central core and outer layer are "softened or melted." Support for this change can be found, for example, on page 9, lines 16 to 20 of the application. Applicant has also amended claim 17 to clarify that the slicing step produces pellets having exposed central cores at opposite ends. Support for this change can be found, for example, in original claim 1 and FIG. 3.

IV. Rejection of Claims Under 35 U.S.C. § 102(b)/103(a)

The Office Action rejected claims 17-21, 23 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Aguadisch (EP 0891769) and Bar-Shalom et al. (US 5618560). Applicant submits that Aguadisch and Bar-Shalom et al., each taken alone, together, or in combination with the other references cited in the case, do not teach or suggest every limitation of independent claim 17, and therefore do not render obvious the claimed invention. Moreover, modifying Aguadisch as suggested by the Office Action would render it unsuitable for its intended purpose. Applicant therefore submits that claim 17, as well as claims 18-21, 23, and 25, which depend on claim 17, are patentable over the prior art of record.

Bar-Shalom et al. relates to controlled release compositions comprised of an inner matrix and an outer coating. The controlled release compositions are prepared by separately mixing the components of the inner matrix and the components of the coating. The resulting inner matrix and coating compositions are subsequently fed to separate extruders (or to the same extruder at different times) to form the controlled release composition. See Bar-Shalom et al. at column 11, line 56 to column 12, line 57 and the examples. Aguadisch relates to a controlled release device that includes a continuous external body, which comprises a first composition and encloses discrete elements of a second composition that contains a pharmaceutical agent. See Aguadisch at Abstract. Like Bar-Shalom et al., Aguadisch describes separately mixing the components of the first and second compositions, which are subsequently fed to separate extruders. See Aguadisch at claim 1 and examples.

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In contrast, the present invention requires feeding the components of the outer layer and central core to extruders, which are used to coextrude the central core and outer layer. Nothing in the references teaches or suggests that the components of the two layers can be fed directly to the extruders. Furthermore, although Bar-Shalom et al. mentions coextrusion of the inner matrix and the coating, all of its examples describe a two-step injection molding process. Since the processes described in Bar-Shalom et al. and Aguadisch are substantially different than the process claimed in the present application, Applicant submits that the claims of the present application are patentable over the references.

Moreover, modifying Aguadisch as described in the Office Action would render it unsuitable for its intended purpose. As a result, Aguadisch cannot be combined with Bar-Shalom et al. since there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) cited in *Manual of Patent Examining Procedure* § 2143.01 (8th ed, Feb. Rev 2003). The process described in Aguadisch requires "periodically restricting the extrusion of the second composition so that at least one element of the second composition with a predetermined volume is extruded within the continuous extrudate body." See Aguadisch at page 2, lines 21 to 23 and claim 1. This results in a device having an outer extruded coating that completely surrounds the pharmaceutical agent-containing core. See Aguadisch at Fig. 3 and Fig. 4. In contrast, Applicant's method results in pellets having exposed central cores at opposite ends. If one were to modify the method in Aguadisch to arrive at Applicant's dosage form, the modified method would not produce a device that completely surrounds the core.

V. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

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Applicant believes that no fees are due with respect to the filing of this amendment. However, if any fees are required in connection with the filing of this paper, please charge deposit account number 23-0455.

Respectfully submitted,

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